

REMARKS

Claims 40-43 have been cancelled, claims 44 and 47 are amended and claims 48-50 are added.

The amendments to claim 44 have support at page 5, lines 17 to 28 of the original specification.

The amendments to claim 47 have support in the original specification at page 7, lines 9 to 14 and page 8, lines 10 to 19 for item (a), at page 7 lines, 14 to 20 and page 8, lines 20 to 30 for item (b), at page 9, lines 13 to 15 for item (f), at page 9, lines 19 to 24 for item (g) and at page 8, lines 2 to 9 for item (h).

As a result, claims 44-50 are pending in the present application.

Unity of Invention

The Examiner maintains the restriction requirement on the basis that the compound 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one is the technical feature of the application that links the claims of groups I and II. Applicants submit that the technical feature that links the two groups of claims is the new crystals of 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-amino-1h-purin-6-(9h)-one prepared by the present process disclosed in the present application characterized by being free from alkaline residues which makes it possible to produce an injectable aqueous solution ready-for-use pharmaceutical formulation, that is sterile and stable, in a closed system, comprised of crystals free from alkaline residues from active principle 9-((1,3-dihydroxypropan-2-yloxy)methyl)-2-mino-1h-purin- 6-(9h)-one as its free acid form diluted in glucose 5% solution or sodium chloride 0.9% solution that presents stability for up to 24 months.

The present claims amendments have been made to create a stronger link between the product and the process claims of the present invention. As a result, the restriction requirement should not be withdrawn.

Specification Objections

As suggested by the Examiner, the title has been amended to a short one. The new title is “STABLE INJECTABLE SOLUTION OF 9-((1,3-DINYDROXYPROPAN-2-YLOXY)METHYL)-2-AMINO-1H-PURIN- 6-(9H)-ONE CRYSTALS FREE FROM ALKALINE RESIDUES”.

Claim Rejections – 35 USC § 103

Claims 44 and 46 have been rejected under 34 USC § 103 over Perillo et al (WO 2004/080371 A2) in view of Smith et al. (USC §378.475).

Claim 45 has been rejected under 35 USC § 103 over Perillo et al. in view of Smith et al. and Gupta et al. (US 2002/0183394 A1).

These rejections are traversed.

The present application claims priority to two Brazilian priority applications, namely PI0305339-3 filed on November 28, 2003 (BR Priority Application A) and PI0405798-8 (Prov.000022040150576) filed on November 23, 2004 (BR Priority Application B). A certified copy of BR Priority Application A was filed and acknowledged by the Examiner. Enclosed with the present reply is a true English translation of the BR Priority Application A. (A sworn English translation will be filed shortly.) This action perfects Applicants' claim to priority based on BR Priority Application A.

Perillo et al. (WO 2004/080371 A1) is, therefore, not citable as prior art because it has a PCT International filing date of 15 March 2004, which is after the filing of the Applicants' first BR Priority Application PI0305339-3 filed on November 28, 2003.

Since Perillo et al. is the Examiner's primary prior art reference cited against the claims, all of the prior art rejections should be withdrawn.

Conclusion

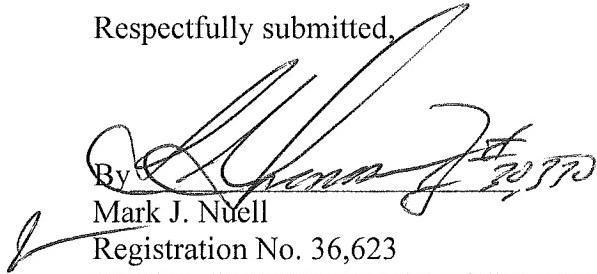
In view of the above, the present application is in condition to be allowed. The applicant respectfully asks that all rejections be withdrawn.

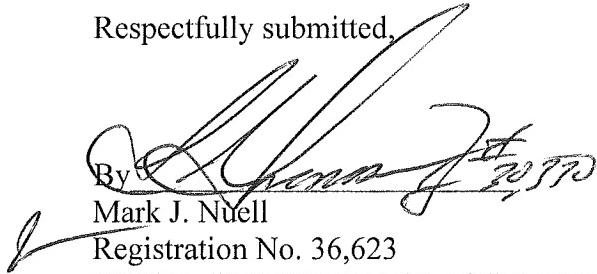
Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petition for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$1,110.00 is attached hereto.

Should there be any outstanding matter that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D. at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Dated: July 23, 2009

Respectfully submitted,



By 

Mark J. Nuell

Registration No. 36,623
BIRCH, STEWART, KOLASCH & BIRCH, LLP
12770 High Bluff Drive, Suite 260
San Diego, California 92130
(858) 792-8855
Attorney for Applicants

Attachments:

Priority document PI 0305339-3
Petition for Extension of Time
Fee Transmittal